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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/533,462 | 03/03/2006 | Yves Mayeresse | VB60410 | 1403 |

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| 20462 | 7590 | 02/06/2008 |
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| EXAMINER | |
| SWARTZ, RODNEY P | |

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| ART UNIT | PAPER NUMBER |
| 1645 | |

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| NOTIFICATION DATE | DELIVERY MODE |
| 02/06/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/533,462

Applicant(s)

MAYERESSE, YVES

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 15-17 is/are allowed.
- 6) ☒ Claim(s) 12-14 and 18-40 is/are rejected.
- 7) ☒ Claim(s) 12, 18 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. Applicant's Response to Non-Compliant Amendment, received 6 April 2007, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, and 39 have been amended. New claim 40 has been added.
2. Claims 1-40 are pending and under consideration.

Notice by Examiner

3. Newly amended claim 20 does not comply with the requirements of 37 CFR 1.121(c). However, in order to expedite the prosecution of this application, the examiner draws applicant's attention to line 2 of the claim. The claim indicates the deletion of the parenthesis in line 2. This deletion was already indicated in the Preliminary amendments of the claims, received 29 April 2005. Correction of the claim into its proper form is required for applicant's next response to Office Action.

Rejections/Objections Withdrawn

4. The objection to claim 1 is withdrawn in light of the amendment of the claim.
5. The objection to claim 12 is withdrawn in light of the amendment of the claim.
6. The objection to claim 13 is withdrawn in light of the amendment of the claim.
7. The objection to claim 14 is withdrawn in light of the amendment of the claim.
8. The objection to claim 16 is withdrawn in light of the amendment of the claim.
9. The objection to claim 17 is withdrawn in light of the amendment of the claim.
10. The objection to claim 24 is withdrawn in light of the amendment of the claim.
11. The objection to claim 27 is withdrawn in light of the amendment of the claim.

12. The rejection of claims 1-22 under 35 U.S.C. 112, second paragraph, as being indefinite for "an" active agent, is withdrawn in light of the amendment of the claims.

13. The rejection of claims 3-11 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitations "step (b)" and "step (c)", is withdrawn in light of the amendment of the claims.

14. The rejection of claims 23-39 under 35 U.S.C. 112, second paragraph, as being indefinite for "highly" viscous, is withdrawn in light of the claim amendments.

15. The rejection of claims 24-39 under 35 U.S.C. 112, second paragraph, as being indefinite for claimed invention, is withdrawn in light of the amendment of the claims.

16. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite for pressure limit, is withdrawn in light of the amendments of the claims.

17. The rejection of claims 23-39 under 35 U.S.C. 112, second paragraph, as being indefinite for preservation of antigenicity/activity, is withdrawn in light of the amendment of the claims.

18. The rejection of claims 1-13 and 15-39 under 35 U.S.C. 112, second paragraph, as being indefinite for concentration, is are withdrawn in light of applicant's arguments and the amendment of the claims.

19. The rejection of claims 23, 27, 28, 29, 31, 35, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Higuchi (U.S. Pat. No. 3,929,132), is withdrawn in light of the amendments of the claims and applicant's argument.

Applicant argues that Higuchi teaches compositions that include up to 80% active agent with additional components in amounts less than about 2% of the weight of the total mixture. Higuchi also discloses addition of inert solids in compositions having a low concentration of

active agent, but does not teach that the disclosed inert solids are glass forming polyol stabilizing agents, or that the inert solids exert any beneficial effect with respect to preventing denaturation, aggregation and/or other means that result in loss of activity of the active agent.

The examiner has considered applicant's argument in light of the amendment of the claims, and finds it persuasive.

Rejections Maintained

20. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for concentration, is maintained for reasons of record.

Applicant argues that based upon Example 2, preservation samples containing concentrations of sucrose from 5% to 25% were dried without boiling or freezing to form a highly viscous liquid. One of ordinary skill in the art could (if desired) easily determine concentrations outside this range which yield comparable glass forming and activity preserving results.

The examiner has considered applicant's argument, but does not find it persuasive for sucrose and trehalose.

The instant claim is drawn to the method of claim 1 which recites that the active agent retain at least 40% of activity, but the instant claim 14 recites that the concentration can be any amount less than 15%.

As previously stated, the specification teaches that any concentration of sucrose less than 10% resulted in 100% loss of activity of the active agent.

Thus, it remains unclear how one utilizes concentrations of sucrose or trehalose less than 10%, but maintain 40% of activity.

21. The provisional rejection of claims 23-33, 36-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 14, 15-18, and 20 of copending Application No. 10/533,464, is maintained for reasons of record.

Applicant respectively requested deferral of the issue of double patenting until such time that the claims in this application or the claims in copending application number 10/533,464 are found to be otherwise allowable.

The examiner has considered applicant's request and maintains the rejection because no terminal disclaimer has been submitted.

Claim Objections

22. Newly amended claims 12 is objected to because of the following informality: in line 2, "the group: of" should be "the group of:" to be consistent with all other claims. Appropriate correction is required.

23. Newly amended claims 18 is objected to because of the following informality: in line 2, "the group of" should be "the group of:" to be consistent with all other claims. Appropriate correction is required.

24. Newly amended claims 22 is objected to because of the following informality: in line 1, "claims" should be "claim". Appropriate correction is required.

Claim Rejections - 35 USC § 112

25. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from claim 37.

Claims 37 is drawn to a solution comprising a mixture of acellular or whole cell Diphtheria antigen, Tetanus antigen and Pertussis antigens.

However, newly amended claim 38 is drawn to a mixture of acellular or "whole Diphtheria antigen, Tetanus antigen and Pertussis antigens". It is unclear what is meant by the deletion of the word "cell". Clarification is required.

27. Claims 13, 19-21, 34, 35, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent from rejected or objected to claims.

Conclusion

28. Claims 12-14 and 18-40 are rejected. Claims 1-11 and 15-17 appear to be allowable.

29. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

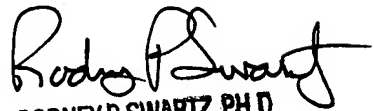
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 30, 2008